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03-28-03

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicant : Anderson et al.
Appl. No. : 09/663,963
Filed : 09/19/00
Title : IMPROVED FERMENTATION PROCESS

Grp./A.U. : 1651
Examiner : K. Srivastava

Docket No. : M6560 OS/OAPT

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Commissioner for Patents
Washington, DC 20231

SUPPLEMENTAL BRIEF ON APPEAL UNDER 37 C.F.R. 1.193(b)(2)(ii)

Sir:

REAL PARTY IN INTEREST

The real party in interest is Cognis Corporation, 2500 Renaissance Blvd., St. 200, Gulph Mills, PA 19406.

RELATED APPEALS AND INTERFERENCES

None.

STATUS OF CLAIMS

Claims 1-3, 6-7 and 10-13 are the subject of this appeal.

STATUS OF AMENDMENTS

No amendments were made after final rejection.

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SUMMARY OF THE INVENTION

Briefly stated, the present invention is directed to a fermentation medium used for making aliphatic-polycarboxylic acids, wherein the medium contains: (a) a source of metabolizable carbon and energy; (b) a source of inorganic nitrogen, (c) a source of phosphate, (d) a metal, and (e) a source of biotin which is substantially free of both particulate matter and bacteria. See page 3, lines 1-10 of the application.

ISSUES

Whether the phrase "substantially free of particulate material and bacteria" present in claim 1(e) is indefinite under 35 U.S.C. § 112, second paragraph.

Whether claims 1-3, 6-7 and 10-13 are anticipated under 35 U.S.C. § 102(b) by Shirai et al., US Patent No. 5,618,708.

Whether claims 1-3, 6-7 and 10-13 are obvious under 35 U.S.C. § 103(a) over Shirai et al., US Patent No. 5,618,708, in view of Pelczar et al. (*Microbiology*, 1977, McGraw Hill Book Company, Pages 110-111 and 428-429).

GROUPING OF THE CLAIMS

The claims stand and fall together.

ARGUMENT

The phrase "substantially free of particulate material and bacteria" is sufficiently definite, as written, and satisfies all of the requirements under 35 U.S.C. 112, second paragraph.

Appellant would like to note that it is well settled that claim terminology is sufficiently definite under 35 U.S.C. § 112, second paragraph, unless there is an unreasonable degree of uncertainty in view of the specification and the art as to what is being claimed. See, In re Johnson and Farnum, 194 USPQ 187, 193 and 194 (CCPA 1977)(emphasis added).

Thus, resort may be had to the usage of terms in the art to determine the definiteness of

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claim terminology. Furthermore, it is also well settled that breadth alone does not make a claim indefinite within the meaning of 35 U.S.C. second paragraph, In re Gardner et al., 166 USPQ 138 (CCPA 1970).

Appellant respectfully submits that the objected-to phrase is clear as to its meaning, as presented, and that it satisfies all of the requirements under section 112, second paragraph. Based on the plain meaning of the words, the biotin should be substantially free of particles which include extraneous materials and contaminants, as well as, bacteria. The meaning of this phrase is eminently clear to those having ordinary skill in the art, when read in light of both the specification and what is known in the art.

Shirai '708 fails to anticipate the claimed invention on the grounds that it fails to disclose each and every element thereof.

Initially, Appellant would like to note that it is well settled that a factual determination of anticipation requires the disclosure, in a single reference, of each and every element of a claimed invention, and an Examiner must identify wherein each and every facet of the claimed invention is disclosed in the applied reference. See, In re Levy, 17 USPQ2d 1561 (Bd. Pat. App. & Inter. 1990).

Appellant has maintained throughout the prosecution of this application that the Shirai reference fails to anticipate the claimed invention on the grounds that it fails to disclose each and every element thereof. More particularly, the Shirai reference fails to disclose the use of a source of biotin **substantially free of both particulate matter and bacteria**, which is an element of the claimed invention.

In response thereto, the Examiner contends that, "...it is common knowledge in the microbiological art that a culture medium is sterilized prior to inoculating it with a particular organism." See, *Paper No. 14*, page 2. On the basis of this premise, the Examiner has maintained his anticipation rejection of the present invention. Appellant respectfully submits, however, that both the premise and the resultant conclusion are defective for the following reasons.

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First and foremost, the claimed invention requires the use of a **sourc** of biotin **substantially free of both particulate matter and bacteria**. Nowhere within the four corners of the Shirai reference is it disclosed to use this ingredient of the claimed invention. For this reason alone, this reference fails to anticipate the present invention.

Secondly, the Examiner has failed to provide any evidence in support of the above-referenced statement relating to the automatic sterilization of culture mediums prior to inoculation. It has been held that, "The Patent Office ... may not, because it may **doubt** that the invention is patentable, resort to speculation, unfounded assumptions or hindsight to supply deficiencies in its factual basis." See, In re Warner, 154 USPQ 173, 178 (CCPA 1967). Clearly, the Examiner's premise is based on nothing more than assumption and speculation based upon the facts contained in the record. To state that it is well known to sterilize a culture medium prior to inoculation, apparently under any and all circumstances known in the microbiological art and **without exception**, requires some proof in support thereof. Since the Examiner has failed to provide any such proof, this reference cannot be held to anticipate the claimed invention.

The Examiner appears to have based his conclusion of anticipation on an inherency theory, i.e., that the culture medium **inherently** contains neither particulate matter nor bacteria because it is automatically sterilized prior to inoculation. The problem with this, however, is that even in the context of inherency, facts must be provided in support thereof for it is extremely well settled that the initial burden of establishing a *prima facie* basis to deny patentability rests upon the Examiner. An Examiner, if relying upon a theory of inherency, must therefore provide a basis in fact to reasonably support a determination that an allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. See, In re Levy, 17 USPQ2d 1461 (Bd. Pat. App. & Inter. 1990).

Moreover, even if the Examiner could prove that **all** culture mediums are, **without exception**, always sterilized prior to inoculation, it must then be shown that this sterilization step results in substantially all of the free particulate matter present in the original biotin source also being removed. It is unclear to Appellant how a sterilization step might result

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in the elimination of particulate matter present in the biotin.

Appellant had also previously argued that whereas the presently claimed fermentation medium **requires** the presence of biotin, a source of phosphate and at least one metal component, in said fermentation medium, the Shirai reference teaches the use of **all** of these components as being **merely optional**. As a result, since this reference fails to **require** the presence of biotin, a source of phosphate and at least one metal component, in its fermentation medium, it cannot serve to anticipate the claimed invention, on the grounds that each and every element of the claimed invention is not disclosed by the prior art reference.

In response thereto, the Examiner countered with the argument that Shirai disclosed a chelating agent and antifoam agent as components of their culture composition, citing col. 6, lines 1 and 31, and then went on to state, "...even though their statement might seem that these components are optional in their culture medium." See, *Paper No. 14*, page 3.

Appellant respectfully submits that neither the Examiner's statement, nor the logic behind it, make any sense to Appellant. Nevertheless, in response thereto Appellant would like to note that it is well settled that an anticipatory reference must clearly and unequivocally disclose the claimed invention or direct those skilled in the art to the claimed invention without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the reference. See, *In re Arkley*, 172 USPQ 524, 526 (CCPA 1972). It is clear that based on this reference's disclosure, a significant amount of picking and choosing would need to occur prior to one of ordinary skill in the art arriving at the claimed invention. Consequently, for this reason as well, the Shirai reference is believed by Appellant to fail to anticipate the claimed invention.

Neither Shirai nor Pelczar, alone or in combination, contains the requisite teaching or suggestion to render the claimed invention prima facie obvious.

Initially, Appellant would like to note that it is well settled that in order to establish

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a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure [underline emphases added]. See, *Manual of Patent Examining Procedure*, Rev. 3, July 1997, § 2142, pages 2100-108. This being said, Appellant respectfully submits that since neither reference teaches or suggests the use of a biotin component substantially free of particulate material and bacteria, i.e., **one of the claim limitations**, a *prima facie* case of obviousness should not be established against the claimed invention.

The shortcomings associated with the Shirai reference are as outlined above. More particularly, Shirai fails to contain any teaching or suggestion relating to the use of a biotin component which is substantially free of particulate matter and bacteria. Nowhere within the four corners of the Shirai reference is it either taught or suggested to employ such a biotin component. Furthermore, even the use of biotin, in general, is taught as being merely optional.

In an effort to overcome the above-identified shortcomings, the Examiner now relies upon the Pelczar reference. This reference teaches that one step in the preparation of bacteriological media involves sterilizing the medium using an autoclave. There are, however, several problems associated with this particular reference's teaching.

First, on page 110 of the reference, it is disclosed that there are various types of media in existence, the choice of which depends on the types of characteristics sought by the user. Differences in the physical state of the media is also a variable. For example, on page 110 of the Pelczar reference it discloses solid, solid-reversible-to-liquid and semisolid media being available.

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Now, the teaching relating to the sterilization of a medium using an autoclave is provided in the context of a powder form media which is first dissolved in water. Based on this teaching, within this context, the Examiner has now somehow assumed that the powder-form media taught by Pelczar is identical to the either the presently claimed medium and/or the Shirai medium. The Examiner then goes on to further assume that Pelczar's powder medium also contains a biotin component. Next, the Examiner assumes that in the event that said powder biotin present in said powder Pelczar medium has any particulate material, that said particulate material will be completely dissolved in the water used to dissolve the powder medium of Pelczar. This logic, however, is flawed on many different obvious levels.

This being said, Appellant would like to note that it has been held that, "The Patent Office ... may not, because it may **doubt** that the invention is patentable, resort to speculation, unfounded assumptions or hindsight to supply deficiencies in its factual basis." See, In re Warner, 154 USPQ 173, 178 (CCPA 1967). Notwithstanding these assumptions, nowhere within those pages of the Pelczar reference provided by the Examiner is it either taught or suggested that:

- (1) the powder-form medium, when dissolved in water, results in any and all particulate matter present therein to be completely dissolved as well; and
- (2) that the autoclaving step is applicable to **ALL VARIETIES/FORMS** of culture media.

However, even if one were to **ASSUME** that all of the Examiner's assumptions are in fact correct, a *prima facie* case of obviousness would nevertheless fail to be established on the grounds that **NEITHER** reference teaches or suggests the use of a biotin component **substantially free of particulate matter and bacteria**. Moreover, since neither reference even addresses the possibility of any particulate matter being present in the biotin component, or in the medium itself for that matter, even if the medium were autoclaved as is advocated by the Examiner that does not mean that any particulate matter present therein would be automatically eliminated as well.

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SUMMARY

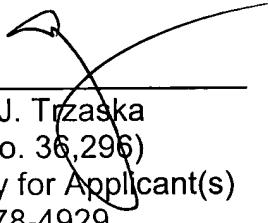
The phrase "substantially free of particulate material and bacteria" is sufficiently definite, as written, and satisfies all of the requirements under 35 U.S.C. § 112, second paragraph.

The Shirai reference fails to anticipate the claimed invention because it fails to disclose each and every element thereof.

Neither Shirai nor Pelczar, alone or in combination, contains the requisite teaching or suggestion to render the claimed invention *prima facie* obvious.

It is requested for the reasons given above, that the Board find for Appellant on all of the issues, and reverse the Examiner's Final Rejections.

Respectfully submitted,



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Enc. Appendix

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APPENDIX

CLAIMS ON APPEAL

1. A fermentation medium comprising:
 - (a) a source of metabolizable carbon and energy;
 - (b) a source of inorganic nitrogen;
 - (c) a source of phosphate;
 - (d) at least one metal selected from the group consisting of an alkali metal, an alkaline earth metal, transition metals, and mixtures thereof; and
 - (e) a source of biotin, substantially free of particulate matter and bacteria.
2. The medium of claim 1 wherein the source of metabolizable carbon and energy is glucose.
3. The medium of claim 1 wherein the source of inorganic nitrogen is ammonium sulfate.
6. The medium of claim 1 wherein the source of phosphate is potassium phosphate.
7. The medium of claim 1 wherein the metal is calcium.
10. The medium of claim 1 further comprising an antifoam agent.
11. The medium of claim 1 further comprising a chelating agent.
12. The medium of claim 1 further comprising at least one trace metal.
13. A fermentation medium comprising:
 - (a) glucose;
 - (b) an ammonium salt;
 - (c) a phosphate salt;
 - (d) a potassium salt;
 - (e) magnesium sulfate;
 - (f) a calcium salt;

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- (g) an ironsalt;
- (h) a chelating agent; and
- (i) a trace metal.